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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/480,472	06/06/95	MCDONOUGH	S 213/066

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HM12/0726

EXAMINER

MARSCHER, A

ART UNIT.

PAPER NUMBER

1655

26

DATE MAILED:

07/26/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/480,472

Applicant(s)
McDonough et al.

Examiner
Ardin Marschel

Group Art Unit
1655



☒ Responsive to communication(s) filed on May 17, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 39-42, 48-51, and 54-142 is/are pending in the application.

~~Of the above, claim(s) 1-38, 43-47, 52, and 53 have been canceled. is/are withdrawn from consideration.~~

☒ Claim(s) 39-42, 48-51, 54-56, 94-100, and 102-142 is/are allowed.

☒ Claim(s) 57, 58, 67-93, and 101 is/are rejected.

☒ Claim(s) 59-66 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1655.

Applicants' arguments, filed 5/17/99, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 67-93 and 101 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 67 and claims dependent therefrom are vague and indefinite due to the phrase in lines 1-2 therein given as "able to bind to or extend through a region". Firstly, is there binding other than hybridization meant? If not, clear claim wording would replace "bind" with "hybridize". Then the phrase states that extending through a region is an alternative to binding. Do applicants wish to indicate that said extending is not inclusive of the ability to bind (hybridize) to a target? but is rather an alternative? Lastly, the phrase "to extend" may be interpreted as either being extended by a polymerase as a primer or that the oligonucleotide has a length that inclusive of a

region of the target nucleic acid. The claim is not clear which of these interpretations is meant. Clarification of the metes and bounds of the claim is requested. Claim 101, part b), also contains the above unclarity.

Claim 74 and claims dependent therefrom are vague and indefinite as to whether the claimed composition is limited to primers or whether hybridization binding ability is an alternative claim embodiment. It is noted that line 1 of claim 74 cites a "composition able to amplify" but that confusingly line 3 cites the phrase "bind to or extend through a region". This line 3 phrase suggests that binding (hybridizing?) is an alternative without requiring extending practice. Thus, hybridization probe only embodiments may reasonably be interpreted as being embodiments of the claim. Also, the above unclarity regarding binding to or extending as summarized in the above paragraph is an unclarity in this claim as well as those dependent therefrom. These same unclarities exist for claims 84 etc.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 57, 58, 67, 68, 74, 75, 84, 85, 92, and 101 are rejected under 35 U.S.C. § 103(a) as being unpatentable over New England Biolabs Products 1101-1108.

This rejection is maintained and reiterated from the previous office action, mailed 1/12/99, except for removing claims 94 and 95 from the list of rejected claims and adding claims 57 and 58 and no longer relying on Sommer et al. Applicants argue regarding the priming reference, Sommer et al. that this teaches a length and 3' terminal complementary character for primers for PCR. This has been found persuasive regarding instant primer only claims or primer only embodiments. The above claims that are listed as being rejected contain

hybridization probe embodiments which suggests the instant claims as described below without requiring primer character in at least one embodiment. See the above 112, second paragraph, rejection regarding the unclarity of claim language that results in one reasonable interpretation of various claims to include probes that are hybridizable to cited sequences thus supporting this rejection as summarized below.

New England Biolabs Catalog Product # 1106 is capable of binding (hybridizing) to instant SEQ ID NO: 23 as follows:

```
SEQ ID NO: 23      5'-CCAGGCCACTTCCGCTAACC-3'
                   |  ||  ||||  ||
Product # 1106     3'-GCTTGGGGAAGCCTAG-5'
```

The above hybridization character results in said Product suggesting the instant claims 67, 68, 74, 75, and 101. The adaptors of the New England Biolabs Catalog suggest instant claims 84, 85, 92, and 101 as follows:

```
SEQ ID NO: 22      5'-GCCGTCACCCACCAACAAGCT-3'
                   |||  || |
Product # 1101:     3'-GGGCCCCTAG-5'
```

The products # 1105 suggest hybridization ability to instant SEQ ID NOs. 3 and 8 as follows as given in instant claims 57 and 58.

```
SEQ ID NO: 3       5'-GTCTTGTGGTGGAAAGCGCTTTAG-3'
                   |  |||  ||
Product # 1105     3'-GCTTCCCCAAGCTTAA-5'
```

```
SEQ ID NO: 8       5'-GGAGGATATGTCTCAGCGCTACC-3'
                   ||  || | |
Product # 1106     3'-GCTTGGGGAAGCCTAG-5'
```

Thus, it would be obvious to someone of ordinary skill in

the art at the time of the instant invention to practice the instant invention because the New England Biolabs products will hybridize to the cited targets in the instant claims as suggested by their sequences as related to said targets above. It is noted that the detectable label of instant claim 92 is present in the Products in that the nucleobases are detectable by UV absorbance.

Claims 59-66 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 39-42, 48-51, 54-56, 94-100, and 102-142 are allowed.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

July 23, 1999

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER